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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/211,297 12/14/98 ROYLE

EXAMINER

U.S. PATENT OPERATIONS
DEPT 430 M/S 27-4-A
AMGEN
ONE AMGEN CENTER DRIVE
THOUSAND OAK CA 91320-1799

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 212

A shortened statutory period for response to this action is set to expire 3 - THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 37-47 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 37-47 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Receipt of the preliminary amendments filed concurrently with this application and on 25 March 1999 is acknowledged. The changes to canceled claims 1-36 instructed in the latter amendment have not been entered.

2. Claim 41 is objected to because of the following informalities. The claim does not conclude with a period, as required under current U.S. practice. Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as now claimed. This rejection concerns the sufficiency of the written description with respect to the subject matter claimed. See the Commissioner's Revised Interim Guidelines published 21 December 1999 at 64 F.R. 71427-71440.

To determine whether there is correspondence between the generic invention of the claims and the written description, it is necessary to determine whether the description conveys to one skilled in the relevant art that applicant was in possession of the claimed genus at the time the application was filed. To this end, it is appropriate to inquire whether a number of species representative of the genus are described in complete structural terms or, alternatively, with reference to other identifying characteristics, *e.g.*, partial structure, chemical properties, functional properties, *etc.* What constitutes a "representative number" of species for any given genus depends in part on whether the level of skill in the art, the teachings in the disclosure, or teachings in the prior art establish a correlation between the structural, functional, or other identifying properties characteristic of the genus.

The disclosure fails to describe any and all "osteoprotegerin binding proteins" and hence the genus of antibodies specific for such proteins. The term "osteoprotegerin binding protein" is defined in the specification at 8 to comprehend any mammalian "OPG binding protein" as well as all

fragments, analogs, and derivatives thereof. The broadest reasonable construction of the term "analog" in this context includes functional as well as structural analogs. The claims are consequently limited only by the osteoprotegerin-binding function of the protein(s) to which the recited antibodies bind.

The only exemplification or otherwise particular identification of such proteins is limited to a single embodiment, *i.e.*, the polypeptide of SEQ ID NO: 7. The claims, however, reasonably appear intended to embrace any antibody which will bind to any protein capable of binding to osteoprotegerin. They thus comprehend antibodies directed to species homologs of the exemplified embodiment, sequence variants thereof, antibodies that bind to osteoprotegerin-binding antibodies, and antibodies wholly unrelated to anything described in the disclosure. The conserved structural features of the genus of binding proteins recited in the claims, which are critical to a description of the antibodies that will bind to them, are nowhere described or suggested in the specification. It is therefore the Office's determination that the description of antibodies specific for a single exemplary polypeptide does not constitute the description of antibodies which are representative of the genera claimed, and hence that the description does not convey to one skilled in this art that the inventors were in possession of the inventions claimed at the time that the application was filed.

4. Claims 37-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 and the claims dependent therefrom are incomplete, vague, and indefinite because it is not clear whether the recited bone resorption need be inhibited within the composition or in any other particular reference system. Amendment of the claim to recite "upon administration thereof to a patient" or the like would obviate this ground of rejection.

Claims 40, 42, 45, and 46 are confusing and indefinite because it is not clear whether they are directed to products (the recited "antibody or fragment") or to compositions subgeneric to those recited in the claims from which they depend. This ground of rejection will be obviated if the claims are amended to recite "The composition of claim *n*, wherein the antibody or fragment"

Claim 42 is incomplete and indefinite because it recites insufficient process steps to prepare an antibody fragment according to claim 41, as required by an alternative embodiment of the claim.

5. All of the claims are patentable over the prior art of record. The exemplified osteoprotegerin binding protein is not described in the prior art, nor are immunogens which would elicit antibodies capable of binding to that protein described.

The art cited but not relied upon is considered pertinent to applicant's disclosure. Ashkenazi *et al.*, U.S. Patent No. 6,046,048, describes monoclonal antibodies which bind to Apo-2L (=TRAIL). As evidenced by Emery *et al.*, *JBC* 273: 14363-67 (1998), TRAIL is a ligand for (and hence binds specifically to) osteoprotegerin. However, the '048 patent does not suggest using the antibodies it describes for the purpose of inhibiting bone resorption, and the available evidence does not support the conclusion that any embodiment described with particularity in the '048 patent would inherently meet the "amount" limitation of the present claims.

7. No claim is allowed.

10. Any inquiry concerning this communication should be directed to Examiner Garnette D. Draper, whose telephone number is (703) 308-4232. Should she not be available, the supervisor for this art unit, Gary Kunz, may be reached at (703) 308-4623. Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.



DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646/1647

for G. D. Draper

28 June 2000